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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,485	02/23/2004	Dusan Mилоjevic	51981/DBP/R178	1783

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,485	MILOJEVIC ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 33-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the invention of Group I in the reply filed on December 12, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The disclosure is objected to because of the following informalities: the missing information on line 34 of page 17 must be supplied.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-9, 11, 12, 15-23, 25, 26 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuzma et al. (Pub. No. US 2003/0125785).

Regarding claim 1, Kuzma et al. disclose a cochlear implant device 10 comprising an elongate member comprising a first insertable portion 20, at least one second portion 30 at least partially supported by the first portion, and movable relative to the first portion such that a distal end of the second portion is moved away from a

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proximal end of the first portion (see Fig. 2B). It should be noted that what is considered a first portion and a second portion is relative and arbitrary.

Regarding claim 4, as one could consider element 30 to be a first portion and element 20 to be a second portion, the first portion is substantially tubular as shown in Fig. 7A. In any event, element 12 is considered substantially tubular. Furthermore, element 20 by virtue of the conductors traveling from the proximal end to the distal end electrodes requires at least a lumen to accommodate the wires and is thus considered to be substantially tubular.

Regarding claim 6, one can say that once implanted, the shape and configuration of the first portion 20 does not substantially change. Whether the shape of the first or second portion changes on insertion is relative to how far the device is inserted.

Regarding claim 7, one can say that the second portion of Kuzma et al. adopts a different configuration to that of the first portion electrode array when it is removed from the cochlea, leaving the first portion in a shape mimicking the cochlea. Lacking specific structural recitations, many other interpretations are possible.

Regarding claims 11 and 12, as stated above, the selection of a first or a second portion is arbitrary. In rejecting claim 11, the examiner will consider element 20 to be a second portion and element 30 to be a first portion, and *vice versa* for claim 12.

The rejections of claims 15-23, 25, 26 and 29-31 parallel the rejections of claims 1-9, 11 and 12.

Regarding claim 32, the examiner considers element 30 to be non-tissue stimulating.

5. Claims 1-4, 6, 7, 9, 11-23, 25-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (Pat. No. 4,261,372).

Regarding claim 1, Hansen et al. disclose a cochlear implant comprising an elongate member comprising a first insertable portion 5, 7, 8, at least one second portion 6 at least partially supported by the first portion, and movable relative to the first portion such that a distal end of the second portion is moved away from a proximal end of the first portion (whether the first and second portion move relative to one another and the direction of movement are immaterial to the rejection of the apparatus claim

since the '372 device is capable of performing such movement). It should be noted that what is considered a first portion and a second portion is relative and arbitrary.

Regarding claim 6, following insertion, the shape or configuration of the first portion does not substantially change since it is confined by the walls of the cochlea.

Regarding claim 7, given that the prongs of the Hansen et al. device are intended for different portions of the cochlea and since the curvature of the cochlea varies along its length, each portion or prong will adopt a different configuration.

Regarding claim 9, as shown in Figs. 2 and 3, the diameter of the distal tip 16 decreases. The intended use of the changing diameter (i.e., to provide a region of friction) was considered, but lacking sufficient structural recitation, failed to saliently distinguish over apparatus that meets the recited structural limitations.

Regarding claim 14, the examiner considers the electrode sets 5b and 6b to be in substantial alignment in the sense that they are both lined up on the same side of the first and second elongate portions and in the same plane. Further, one could argue that depending on one's perspective, the electrodes may be substantially aligned.

The rejection of claims 15-23 and 25-31 either parallel the rejection of similarly worded claims discussed above, or are clearly established by the reference itself.

Regarding claim 32, the examiner considers the first portion to be non-tissue stimulating in areas absent the electrodes. Also, one can say that the first portion is non-tissue stimulating when no stimulation energy is being transmitted to the electrodes.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 10 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. '785 in view of Kuzma et al. (Pat. No. 6,309,410).

Kuzma et al. '785 do not discuss the use of an elongate member with a channel or reservoir for the delivery of at least one bioactive substance. Kuzma et al. '410, however, do disclose such a feature for delivering drugs deep into the cochlea (see col. 6, lines 3-17). The advantages of allowing drug treatment of select areas of the cochlea are obvious. Whether or not a device incorporates such a delivery system is clearly dependent upon the particulars of the individual under treatment. To include such a feature on the '785 invention would have therefore been considered a matter of obvious design to those looking to maximize treatment effectiveness in view of the '410 patent.


Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaeetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
February 14, 2007


KENNEDY SCHAEETZLE
PRIMARY EXAMINER